UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

THE JUDGE ROTENBERG EDUCATIONAL CENTER, INC., *Petitioner*, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., *Respondents*.	No. 20-1087 (Consolidated with No. 20-1088)

PETITIONER'S STATEMENT OF ISSUES TO BE RAISED

Pursuant to the Court's Order dated March 27, 2020, Petitioner The Judge Rotenberg Educational Center, Inc. (JRC) hereby submits this non-binding, preliminary statement of issues to be raised in its Petition, which seeks review of a final regulation issued by the U.S. Food and Drug Administration (FDA) banning electrical stimulation devices used to treat aggressive or self-injurious behavior, published in the Federal Register on March 6, 2020 at 85 Fed. Reg. 13312 (the Final Rule).

1. Whether the Final Rule must be vacated and set aside because it is unsupported by substantial evidence on the record taken as a whole pursuant to 21 U.S.C. § 360g(c) and 5 U.S.C. § 706(2)(E).
2. Whether the Final Rule must be vacated and set aside because it is, *inter alia*,

arbitrary, capricious, an abuse of discretion, because FDA did not consider "all available data and information", or otherwise not in accordance with law pursuant to, *inter alia*, 21 U.S.C. §§ 360f(a), 360g(c), § 360g(e); 5 U.S.C. § 706(2); and the Due Process and Equal Protection Clauses of the Fifth Amendment to the United States Constitution.

3. Whether the Final Rule must be vacated and set aside because it rests on a contrived, pretextual rationale, and is the product of agency bad faith and/or improper behavior and a predetermined, outcome-driven, unfair process.

4. Whether the Final Rule must be vacated and set aside because it exceeds FDA's statutory jurisdiction and authority and impermissibly limits and interferes with the practice of medicine, State regulation of the practice of medicine and valid State court orders authorizing the treatment at issue, and the authority of a healthcare practitioner to prescribe or administer the subject Graduated Electronic Decelerator ("GED") device to a patient within a legitimate health care practitioner-patient relationship.

Respectfully submitted,

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Dated: April 24, 2020 *Counsel for Petitioner*

CERTIFICATE OF SERVICE

I hereby certify that on April 24, 2020, I caused a copy of the foregoing document to be served on the below counsel by filing it with the Court's electronic filing system:

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